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In Re the Application of:

BRENNAN et al.

Serial No.: 09/458,580

Filed: December 9, 1999

Atty. File No.: 3718-3

For: "COMPOSITION AND METHOD
FOR REGULATION OF BODY
WEIGHT AND ASSOCIATED
CONDITIONS"

Assistant Commissioner for Patents
Washington, D.C. 20231

Group Art Unit: 1655

Examiner: Souaya, J.

FEB 19 2002

TECH CENTER 1600/2900

RESPONSE TO
RESTRICTION REQUIREMENT

#13
2/23/02
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SHERIDAN ROSS P.C.

BY: *Atul Kumar*

Dear Sir:

This response is filed in response to a Restriction Requirement having a mailing date of October 5, 2001. This response is believed to be timely and therefore, no fees are enclosed. In the event that fees are due in connection with this response, please debit Deposit Account No. 19-1970.

The Examiner has restricted the claims of the invention into five groups as follows:

Group I (Claims 1, 4-10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103 and 108-114), directed to a method of decreasing or increasing body weight in an animal; Group II (Claims 66-67), directed to a method for regulating metabolic efficiency in an animal; Group III (Claims 70, 72-74, 80-82, 85-91 and 93-94), directed to a therapeutic composition; Group IV (Claim 95), directed to a method for treating an affective and mood disorder; and Group V (Claim 100), directed to a method for treating a reproductive disorder.

Applicants provisionally elect, with traverse, to prosecute the claims of Group I (Claims 1, 4-10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103 and 108-114).

Applicants traverse the restriction between Groups I, II and III. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803. Applicants submit that a thorough search for Group should also include the subject matter of Groups . In the present case, the subject matter of these Groups cited by the Examiner is sufficiently small and is so closely related as to be capable

of examination together. The restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office.

More specifically, the claims of Group I are drawn to a method for increasing or decreasing weight and the claims of Group II are directed to a method for regulating metabolic efficiency in a mammal. Applicants submit that Groups I and II are closely related in that Group II is directed to a mechanism of action that is associated with weight regulation (e.g., Group I), wherein there is an extra step, as compared to Group I, of measuring the MSH level in the animal to identify particular candidates. It is submitted that it would not place an undue burden on the Examiner to search and examine the claims of Group II with the claims of Group I. Therefore, Applicants respectfully request that the Examiner withdraw the restriction between the claims of Groups I and II.

With regard to Group III, the Examiner contends that product of Group III can be used in a materially different process, which is stated to be to select and identify compound specific binding partners. However, Applicants submit that the claimed composition is clearly not intended for use in a method to select and identify compound specific binding partners. Claim 68, the independent claim of Group III (note that it appears that Claim 68 should be included with Group III), recites a therapeutic composition comprising: (a) a melanocyte stimulating hormone (MSH) compound selected from the group consisting of MSH and an MSH agonist; and, (b) a body weight regulating agent that is not a MSH compound. Applicants fail to see how the combination of the *body weight regulating* compound in combination with the MSH compound, which are disclosed for use in the method to regulate body weight, are useful for another materially different process, and the Examiner has not provided a reasonable explanation of the same. Therefore, at a minimum, Applicants respectfully request that the Examiner withdraw the restriction between the claims of Groups I and III.

Respectfully submitted,

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Date: October 24, 2001